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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/825,155 | 04/03/2001 | Ariel Ruiz i Altaba | 1049-1-008 N CON | 2618 |

23565 7590 07/02/2002

KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER

BUI, PHUONG T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 07/02/2002

1/1

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,155

Applicant(s)

Altaba

Examiner

Phuong Bui

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to a method for the detection of BBC, classified in class 435, subclass 70.1.
 - II. Claim 4, drawn to an assay for the detection of BBC, classified in class 435, subclass 325.
 - III. Claims 5-6, drawn to a method of modulating the activity of Gli1, classified in class 435, subclass 7.1.
 - IV. Claim 7, drawn to a test kit, classified in class 435, subclass 810.
 - V. Claim 8, drawn to a method of preventing and/or treating disease states using Gli1 inhibitors, classified in class 424, subclass 139.1.
 - VI. Claim 8, drawn to a method of preventing and/or treating disease states using a specific binding partner, classified in class 424, subclass 130.1.
 - VII. Claim 9, drawn to a pharmaceutical composition comprising inhibitors of Gli1 activity, classified in class 530, subclass 350.
 - VIII. Claim 9, drawn to a pharmaceutical composition comprising a specific binding partner, classified in class 530, subclass 387.1.
2. The inventions are distinct, each from the other because of the following reasons:

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Inventions I, II, III, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions as they are directed to different method and utilizes different materials and have different outcomes.

Inventions IV, VII and VIII are unrelated. In the instant case the different inventions have different functions as they are directed to structurally different products and are used in different methods.

3. Inventions VII-VIII and V-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of inventions VII-VIII can be used in vitro for diagnostic and testing purposes.

4. Other inventions directed to methods and inventions directed to products not addressed above are unrelated since these methods do not require the products of inventions IV, VII and VIII. The methods of I-II do not require the test kit of IV since the methods of I-II do not require a detectably labeled specific binding partner to Gli1 as set forth in IV. Further, the test kit of IV has a different mode of operation from the method of modulating the activity of Gli1 of III.

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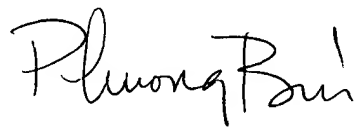
Similarly, the pharmaceutical composition of VII-VIII has a different mode of operation from the methods for detection and the method of testing of I-III.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, searches, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996.

ptb
June 29, 2002


PHUONG T. BUI
PRIMARY EXAMINER